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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,166	12/02/2005	Gerd Seibold	31698-01311	8236
71/040 7590 04/01/2008 LUCÉ, FORWARD, HAMILTON & SCRIPPS 11988 EL CAMINO REAL, SUITE 200 SAN DIEGO, CA 92130				
EXAMINER				
BLATT, ERIC D				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,166

Applicant(s)

SEIBOLD ET AL.

Examiner

Eric Blatt

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 25-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 30-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

Acknowledgement is made of Applicant's amendment submitted January 3, 2008 amending the specification to correct minor typing errors, affirming the election of Group I, by which claims 25-29 have been withdrawn, and amending independent claims 1, 14, and 30.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 7, 11, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al (US 6,080,182).

Regarding claim 1, 4, 6, 7, 11, and 40 Shaw et al discloses a device for sealing a puncture extending through tissue proximal to an interior vessel surface, the device comprising a first disk (the first end of sealing device 132) having a self-expanding frame that forms a plurality of petals (Figures 8A-8F); and a proximal element comprising a second disk (the second end of sealing device 132). In Applicant's Arguments submitted January 3, 2008, Applicant pointed to Figure 3 of Shaw et al, which shows the construction of the first and second disks wherein a membrane is

applied to first and second bare wire frames. Applicant correctly points out that many of embodiments, including those relied upon shown in Figures 22A-22G, the first and second frames are connected to one-another via their respective membranes. While the first and second frames do not immediately contact one-another, this connection between the first and second frames constitutes a coupling between said frame nonetheless. Additionally, Shaw et al teaches alternate embodiments in which the first and second frames are more directly coupled to one another. (Figures 32A and 32B) The device has a retracted delivery configuration adapted for delivery to the puncture, and a deployed configuration in which the first disk is adapted to engage and substantially conform to the interior vessel surface, and the proximal element is configured to engage the tissue. (Figures 22A-22G)

There is a minimally invasive delivery apparatus (Figure 36) comprising first and second delivery elements 216, 222 configured to at least selectively limit distal translation of the first delivery element with respect to the second delivery element so that only the first disk is extended out of the minimally invasive delivery apparatus. (Column 17, Lines 16-30) There is at least one delivery shaft 80 configured to facilitate coupling of the first disk to the proximal element, (Figures 22A-22-G) and at least one delivery element constrained to translate a maximum distal depth. (Figure 36, Column 17, Lines 16-30). The proximal element comprises a spring (Figure 40D). There is a membrane encasing at least the self-expanding frame of the first disk. (See Abstract)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2-3, 5, 8, 10, 13-16, 18-24, and 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al et al (US 6,080,182) in view of Stevens et al (US 5,797,960).

Regarding claims 2-3, 5, 8, 9, 14-16, 18-23, and 24, Shaw et al discloses a device for sealing a puncture extending through tissue proximal to an interior vessel surface, the device comprising a first disk (the first end of sealing device 132) having a self-expanding frame that forms a plurality of petals (Figures 8A-8F); and a proximal element comprising a second disk (the second end of sealing device 132) having a second self-expanding frame coupled to the first disk. In Applicant's Arguments submitted January 3, 2008, Applicant pointed to Figure 3 of Shaw et al, which shows the construction of the first and second disks wherein a membrane is applied to first and second bare wire frames. Applicant correctly points out that in many of the embodiments, including those relied upon that are shown in Figures 22A-22G, the first and second frames are connected to one-another via their respective membranes. While the first and second frames do not immediately contact one-another, this connection between the first and second frames constitutes a coupling between said frame nonetheless. Additionally, Shaw et al teaches alternate embodiments in which

the first and second frames are more directly coupled to one another. (Figures 32A and 32B) The device has a retracted delivery configuration adapted for delivery to the puncture, and a deployed configuration in which the first disk and second disks are adapted to engage and substantially conform to the interior vessel surface, and the proximal element is configured to engage the tissue. (Figures 22A-22G) The second self-expanding frame forms a plurality of petals. (Figures 8A-F)

Shaw et al also discloses a minimally invasive delivery apparatus (Figure 36) comprising first and second delivery elements 216, 222 configured to at least selectively limit distal translation of the first delivery element with respect to the second delivery element so that only the first disk is extended out of the minimally invasive delivery apparatus. (Column 17, Lines 16-30) There is at least one delivery shaft 80 configured to facilitate coupling of the first disk to the proximal element, (Figures 22A-22-G) and at least one delivery element constrained to translate a maximum distal depth. (Figure 36, Column 17, Lines 16-30)

As previously discussed, the proximal element comprises a spring (Figure 40D); and there is a membrane encasing at least the self-expanding frame of the first disk. (See Abstract)

Shaw et al does not disclose that the device, including the first and second disks, are configured to be released from engagement with the interior vessel surface after deployment of the device, thereby permitting the device to be repositioned wherein the at least one delivery shaft is configured to facilitate coupling and decoupling of the first disk from the proximal element. Shaw et al also does not disclose that the first disk is

attached to a nut and the second disk is attached to a bolt, the nut configured to be releasably coupled to the bolt.

Stevens et al discloses a similar system for sealing a puncture comprising a first disk attached to a nut and the second disk attached to a bolt, the nut configured to be releasably coupled to the bolt (Figures 10-14, Columns 4-5, Column 20) wherein at least one delivery shaft is configured to facilitate coupling and decoupling of the first disk from the proximal element. (Figures 10-14, Columns 4-5, Column 20) Thus, the sealing device, including the first and second disks, are configured to be released from engagement with the interior vessel surface after full deployment of the device, thereby permitting the device to be repositioned. (Figures 10-14, Columns 4-5, 20, 25)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Shaw et al by providing the attachment mechanism disclosed in Stevens et al for purposes such as allowing the sealing device to be repositioned if the first deployment position is unsatisfactory as taught by Stevens et al. (Column 25, Lines 4-17)

Regarding claims 10,13, 30-36, and 37-39, 37, Shaw et al does not disclose that at least part of the device is biodegradable. Shaw et al additionally does not disclose that one or both of the first disk and the proximal element comprises barbs, hooks, sharp edges, or roughened surfaces.

Stevens et al discloses that it was well known to have at least part of the device is biodegradable (Column 22, 18-23), and that one or both of the first disk and the proximal element may comprise barbs, hooks, sharp edges, or roughened surfaces. (Figures 10-15, Column 20, Lines 27-48) It would have been obvious to one of ordinary

skill at the time of the invention to further modify the apparatus of Shaw et al by having at least part of the device be biodegradable for purposes such as allowing components to biodegrade as the tissue heals as taught by Stevens et al. Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus of Shaw et al by providing barbs, hooks, or sharp edges to aid the closure device in engaging the vessels walls as taught by Stevens et al.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al et al (US 6,080,182) in view of Van Tassel et al (US 6,949,113).

Regarding claim 12, Shaw et al discloses all elements of claim 12 as previously discussed except a coagulant-enhancing agent that is disposed on one or both of the first disk and the proximal element. Van Tassel et al discloses device for sealing an opening in a blood vessel comprising a coagulant-enhancing agent that is disposed on a disk. (Column 12, Lines 20-24) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Shaw et al by providing a coagulant-enhancing agent that is disposed on one or both of the first disk and the proximal element to prevent blood from passing through the sealed puncture as taught by Van Tassel et al.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al et al (US 6,080,182) in view of Stevens et al (US 5,797,960) as applied to claim 14 above, and further in view of Van Tassel et al et al (US 6,949,113).

Regarding claim 17, Shaw et al discloses all elements of claim 17 as previously discussed except a coagulant-enhancing agent that is disposed on one or both of the first disk and the proximal element. Van Tassel et al discloses device for sealing an opening in a blood vessel comprising a coagulant-enhancing agent that is disposed on a disk. (Column 12, Lines 20-24) It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus of Shaw et al by providing a coagulant-enhancing agent that is disposed on one or both of the first disk and the proximal element to prevent blood from passing through the sealed puncture as taught by Van Tassel et al.

Response to Arguments

Applicant's arguments filed January 3, 2008 have been fully considered but they are not persuasive.

Applicant argues that Shaw et al does not teach first and second bare wire frames that are coupled to one another. Applicant points to Figure 3 of Shaw et al, which shows the construction of the first and second disks wherein a membrane is applied to first and second bare wire frames. Applicant correctly points out that in many of the embodiments including those relied upon that are shown in Figures 22A-22G, the first and second frames are connected to one-another via their respective membranes. While the first and second frames do not immediately contact one-another, this connection between the first and second frames constitutes a coupling between said frames nonetheless. Additionally, Shaw et al teaches alternate embodiments in which

the first and second frames are more directly coupled to one another. (Figures 32A and 32B)

Applicant also argues that the embodiments shown in Figures 40C and 40D do not constitute petals. Looking at the terminal disks in Figure 40D, there appear to be petals formed on said disks. Alternatively, Shaw et al also teaches a number of frame configurations which include petals. (Figures 8A-8F) It would have been obvious to one of ordinary skill in the art at the time of the invention to use one of said frame configurations for the terminal disks since Shaw et al teaches that such configurations are acceptable alternatives.

Applicant contends that the limitation that "the device is configured to be released from engagement with the interior vessel surface after full deployment of the device" (Claims 14-24) was not addressed in the First Action on the Merits and is not taught by Shaw et al. This limitation has been addressed in both the first action and the present action, and while said limitation is not taught by Shaw et al, it is taught by Stevens et al as has been previously discussed.

Finally, Applicant argues that Stevens et al does not teach a first disk attached to a nut and a second disk attached to a bolt. Figures 10-14 are cited as showing a first disk attached to a nut and a second disk attached to a bolt. Applicant contends that rather than teaching a nut and a bolt, Stevens et al teaches a "hub 146 having a threaded hole 160, in which the threaded distal end of an inner control rod 140 may be threaded." Said hub 146 having a threaded hole 160 is considered a nut. Said inner control rod 140 having a threaded distal end is considered a bolt.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Blatt
571-272-9735

/Todd E Manahan/
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